

A4. 510(k) Summary

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510(k) SUMMARY

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Proprietary names:

- I) Needles for bone-marrow biopsy
- II) Semiautomatic guillotine needles for soft-tissue biopsy
- III) Automatic guillotine needles for soft-tissue biopsy

Common name: Biopsy needle kit

Classification name: 21 CFR 876.1075 -Instrument, Biopsy

Device class: II

Classification panel: Gastroenterology / Urology

Product code / procode: KNW / FCG

Indication for use statement: The medical devices object of this 510K are all needles for biopsy. The products could be classified in 3 families that are:

- the needles for bone-marrow biopsy (In this family of needles for bone-marrow biopsy there is also a little group of devices intended for bone-marrow explants).

In particular the indications for use for each different model are the followings:

OSTEOBELL 'T': Needle for bone-marrow biopsy
ORION: Needle for bone-marrow biopsy
ILIAC-MARROW: Needle for bone-marrow biopsy
OBSTERN: Needle for bone-marrow biopsy
STERNOBELL: Needle for bone-marrow biopsy
TOTALLY REMOVE: Needle for bone-marrow biopsy
UNLUX SYSTEM: Needle for bone-marrow biopsy
OSTEOBELL EXPLANT: Needle for bone-marrow explant
ORION EXPLANT: Needle for bone-marrow explant
ILIAC-MARROW EXPLANT: Needle for bone-marrow explant
OBSTERN EXPLANT: Needle for bone-marrow explant
STERNOBELL EXPLANT: Needle for bone-marrow explants

- the semiautomatic guillotine needles for soft-tissue biopsy (breast, kidney, liver, prostate):

SPEEDYBELL: semiautomatic guillotine needle for soft-tissue biopsy (breast, kidney, liver, prostate)
SPEEDYBELL DOPPIA CORSA: semiautomatic guillotine needle for soft-tissue biopsy (breast, kidney, liver, prostate)
SPEEDYBELL & INTRODUTTORE: semiautomatic guillotine needle for soft-tissue biopsy (breast, kidney, liver, prostate)
SPEEDYBELL DOPPIA CORSA & INTRODUTTORE: semiautomatic guillotine needle for soft-tissue biopsy (breast, kidney, liver, prostate)

- the automatic guillotine needles for soft-tissues biopsy (liver):

ESTER: automatic guillotine needle for soft-tissue biopsy (liver)
ESTER & INTRODUTTORE: automatic guillotine needle for soft-tissue biopsy (liver)

Description of the device:

The medical devices object of this 510K are all needles for biopsy, used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination (biopsy). The devices could be classified in 3 families that are:

- the needles for bone-marrow biopsy,
- the semiautomatic guillotine needles for soft-tissue biopsy and
- the automatic guillotine needles for soft-tissue biopsy.

All the needles are single use and sterile (ETO sterilization).

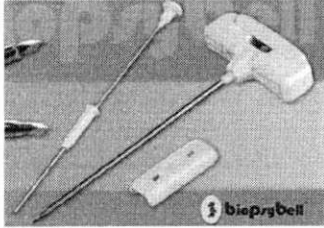
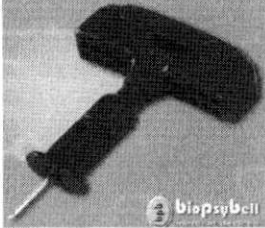
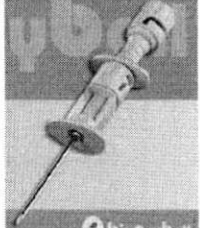
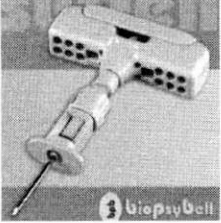
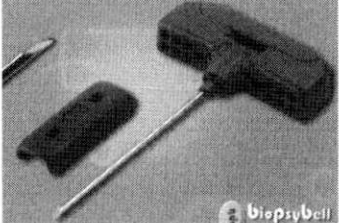
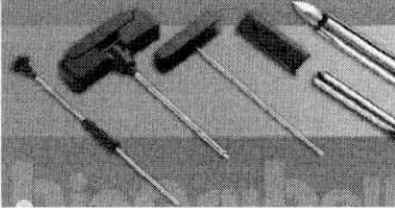
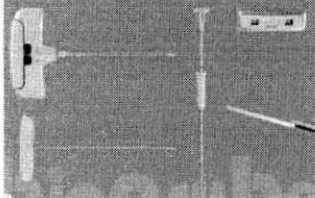
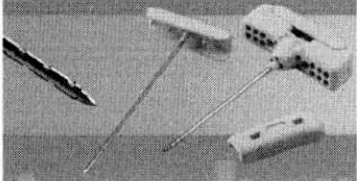
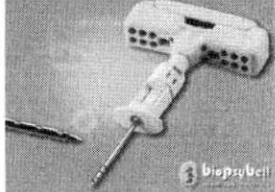
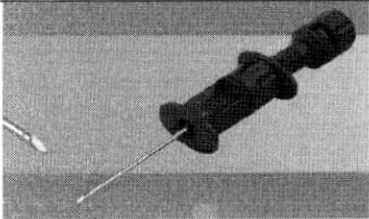
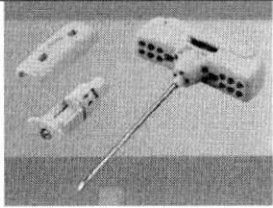
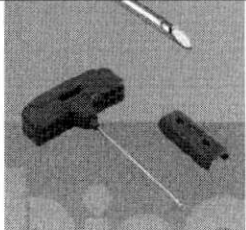
All the needles are composed with an external cannula (tube) and an internal stylet (mandrel) both in AISI 304

stainless steel. The grip of the needles is in plastic (different depending from the model).

1) Needles for bone-marrow biopsy

Product description: Needles for bone-marrow biopsy. These needles are intended for bone-marrow biopsy. All needles are made from AISI-304-stainless-steel in conformity with the requirements of ISO 9626 and ASTM F899-02 and the grip is in ABS (Acrylonitrile-Butadiene-Styrene).

The needle is individually packed in rigid plastic blister and medical paper and is sterilized by ethylene oxide (ETO) in compliance with ISO 11135 requirements. It is sold in packs of 5 or 10 pieces. The device is not reusable. The design of the needles is mostly identical and differ only in little details. The different models of needles for bone-marrow biopsy are the followings:

<p>OSTEOBELL 'T'</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Extractor - Needle with 'trocar tip' - Luer lock connection 	<p>ORION</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'trocar tip' - Ring nut (depth limiter) - Luer lock connection 	<p>STERNOBELL</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'triple sharpened' tip - Ring nut (depth limiter) - Luer lock connection
<p>ILIAC MARROW</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'triple sharpened' tip - Ring nut (depth limiter) - Luer lock connection 	<p>OBSTERN</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'triple sharpened' tip - Luer lock connection 	<p>TOTALLY REMOVE</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Extractor - Needle with 'trocar tip' - Luer lock connection - Anti-dislocation cannula
<p>UNLUX SYSTEM</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Extractor - Needle with 'trocar tip' - Luer lock connection - Anti-dislocation stylet 	<p>OSTEOBELL EXPLANT</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Second additional stylet - Needle with 'trocar tip' - Luer lock connection - Holes in the distal part of cannula 	<p>ORION EXPLANT</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'trocar tip' - Ring nut (depth limiter) - Luer lock connection - Holes in the distal part of cannula - Second additional stylet
<p>STERNOBELL EXPLANT</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'triple sharpened' tip - Ring nut (depth limiter) - Luer lock connection 	<p>ILIAC MARROW EXPLANT</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'triple sharpened' tip - Ring nut (depth limiter) 	<p>OBSTERN EXPLANT</p>  <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Needle with 'triple sharpened' tip - Luer lock connection

- Holes in the distal part of cannula	- Luer lock connection - Holes in the distal part of cannula	- Holes in the distal part of cannula
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Explanation of how the device functions. All the devices are intended for bone-marrow biopsy. Each device has a specific functioning depending from each specific feature. All the specific instructions for use are reported in each Sheet with Instructions for use. The principle of functioning of the needles is reported below: After the patient has been positioned and prepared, the needle is inserted with the stylet through the external part of the bone until finding the least resistance (which indicates entry into the medullar cavity). Depending from the type of needle, the collection of the sample can be realized in two ways:

- by aspirating the medullary tissue, attaching a syringe to the luer-lock connection of the needle grip;
 - by detaching a fragment of medullary tissue with the distal part of the needle. In this case the fragment of tissue is collected on the slide by using the 'extractor' present in the kit.
- In some cases there is also a depth limiter to be adjusted in order to select the depth to be reached with the needle in the patient.


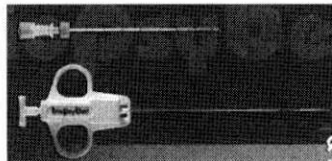

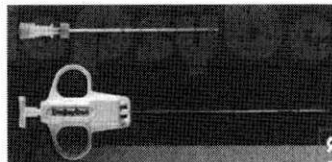
I) Semiautomatic guillotine needles for soft-tissue biopsy

Product description: Semiautomatic guillotine needles for soft-tissue biopsy (such as: breast, kidney, liver, prostate).

All needles are made from AISI-304-stainless-steel in conformity with the requirements of ISO 9626 and ASTM F899-02 and the grip is in PC (Polycarbonate).

The needle is individually packed in a medical-grade paper bag and is sterilized by ethylene oxide (EtO) in compliance with ISO 11135 requirements. It is sold in packs of 10 pieces. The device is not reusable.

The design of the needles is mostly identical and differ only in little details.
The different models of needles are the followings:

SPEEDYBELL	SPEEDYBELL & INTRODUTTORE
 <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Notch of 2cm 	 <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Notch of 2cm - Introducer needle
SPEEDYBELL DOPPIA CORSA	SPEEDYBELL DOPPIA CORSA & INTRODUTTORE
 <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Notch of 1 cm or 2cm 	 <p>Components:</p> <ul style="list-style-type: none"> - Cannula - Stylet - Plastic grip - Notch of 1 cm or 2cm - Introducer needle

Explanation of how the device functions: All the devices are semiautomatic guillotine needles for soft-tissue biopsy. Each device has a specific functioning depending from each specific feature. All the specific instructions for use are reported in each Sheet with Instructions for use. The principle of functioning of the needles is reported below:

- Position two fingers of one hand in the rings and with the other hand pull the rear knob until hearing a click as the spring catches, indicating that the needle has been loaded.
- Insert the needle in the point selected for biopsy.
- When the needle is in place push the rear knob until the end of the stroke.
- Firmly push the rear knob, which will make a final click, to remove the material to be analysed.
- Extract the needle from the patient tissue.
- To retrieve the fragment drawn and analyse it, repeat the loading manoeuvre pulling the rear knob until hearing the spring catch. Then slowly push the knob for $\frac{3}{4}$ of its travel; in this way the needle emerges and the bioptic material can be transferred to the slide.
- In the needles with the Introducer, the Introducer has to be inserted at the beginning of the procedure, the stylet extracted and the Speedybell inserted through the cannula of the Introducer. Then, the Introducer has to be removed at the end of the procedure.
- In the Speedybell Doppia Corsa the doctor can chose between a sampling area of 1cm or 2cm.

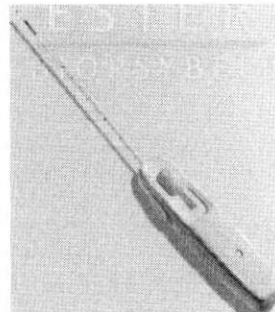
II) Automatic guillotine needles for soft-tissue biopsy

Product description: Automatic guillotine needles for soft-tissue biopsy (liver)

All needles are made from AISI-304-stainless-steel in conformity with the requirements of ISO 9626 and ASTM F899-02 and the grip is in ABS (Acrylonitrile-Butadiene-Styrene).

The needle is individually packed in a rigid plastic blister and medical paper and is sterilized by ethylene oxide (ETO) in compliance with ISO 11135 requirements. It is sold in packs of 5 pieces. The device is not reusable.

The different models of needles for bone-marrow biopsy are the followings: ESTER and ESTER & INTRODUTTORE.



ESTER is a fully automatic, single-use device particularly suitable for liver biopsies.

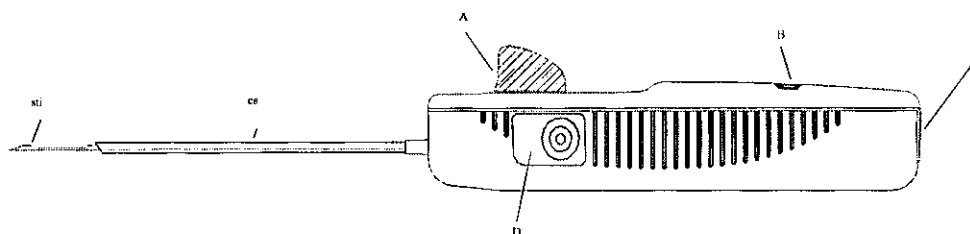
The characteristics that mark ESTER are:

1. Only one button to load the cannula and the stylet. This system allows the physician to use the device with only one hand for greater practicality and convenience leaving the other hand free to use the ultrasound scanner.
2. Two shooting buttons to choose from, one on the side and one on the rear, whichever the physician finds more comfortable.
3. The physician is given the choice of two alternative shooting options:
 - 3.1 Automatic selectable: lightly pressing the shooting button to move only the stylet forward thus exposing the sampling cavity outside the cannula and then fully pressing it down to let the cannula move forward. In this way, shooting is done with two distinct actions and the time between one and the next can be decided by the physician.

3.2 Automatic: fully pressing down the shooting button to simultaneously move the stylet and the cannula forward.

In this way, shooting is done with one single action, but the stylet and the cannula move forward at slightly staggered times.

Explanation of how the device functions: The devices are automatic guillotine needles for soft-tissue biopsy. The specific instructions for use are reported in the Sheet with Instructions for use. The principle of functioning of the needles is reported below:



- Load the needle by pushing down on the central loading lever (A) with your thumb or index finger sideways as far as it will go and then release it to allow it to return to its initial position. In this way the needle cannula is loaded.
- Repeat this operation a second time, i.e. push down on the same lever again as far as it will go and then release it to allow it to return to its initial position.
- In this way the stylet is loaded and a visual sign can be seen in the rear hole (B) indicating that loading is complete.
- Insert the tip of the needle in the target selected for the biopsy and follow the biopsy under ultrasound guidance.
- Continue with shooting by pressing the rear button (C) or the side button (D), whichever is more comfortable for the physician, and in both cases, choose from the following two alternatives:
 1. Lightly press the shooting button without pushing it fully down so that only the stylet moves forward thus exposing the sampling cavity outside the cannula. Then fully press down the button to let the cannula move forward.
In this way, shooting is done with two distinct manual actions and the time between one and the next can be decided by the physician.
 2. Fully press down the shooting button. In this way, you can simultaneously move the stylet and the cannula forward with one manual action (the stylet and the cannula move forward at slightly staggered times).
- Slowly remove the needle from the patient.
- To retrieve the fragment contained in the cavity in proximity of the needle tip, push down on the central loading lever (A) as far as it will go and then release it to allow automatic return to its original position. (Warning: unlike the initial needle loading operation, to retrieve the fragment, the loading lever needs to be pushed only once and not twice).
- Finally, once the sampling area containing the fragment has been uncovered, scrape the sample taken onto a slide.
- In the model with the Introducer needle, the Introducer has to be inserted at the beginning of the procedure, the stylet extracted and the Ester inserted through the cannula of the Introducer. Then, the Introducer has to be removed at the end of the procedure.

Bench tests/Clinical tests: Non clinical tests concerning the functionality and efficiency were performed on the products because Biopsybell performed specific bench tests for each device family. All the tests are detailed in the Test report n°59/10 dated 08/11/2010 for the needles for bone-marrow biopsy, Test report n°67 dated 08/11/2010 for semiautomatic guillotine needles for

soft-tissue biopsy, Test Report n° 68 dated 30/04/2012 for Automatic guillotine needles for soft-tissue biopsy.

The purpose of the tests was to demonstrate the suitability of the device for its intended use. In each test were used animal and artificial tissues/conditions comparable or worst cases on respect to the 'in vivo' situation. The use of the needles was tested. All the tests demonstrated that all the devices are fully compliant in matter of effectiveness and safety.

Here there is a brief description of the tests performed.

Test report n°59/10 dated 08/11/2010 for the needles for bone-marrow biopsy

The Biopsybell Needles for bone marrow biopsy collect bone marrow samples by needle insertion. Hemopoietic tissue biopsy consists in the sampling of a small marrow amount by use of a large needle. The sample is then dyed and submitted to microscopical examination.

The purpose of testing is to evaluate:

- 1) The needle stylet perforation capacity in the bone.
- 2) The Needles for bone marrow biopsy Cannula perforation capacity in the bone tissue.
- 3) The handle grip during bone insertion procedures.
- 4) The adequacy of the Luer-lock connection.
- 5) The quantity of the collected sample.
- 6) The integrity of the collected sample.

For the present report have been used 2 model of products that are the worst case of all the other models of needles of Biopsybell. The first device is ILIAC MARROW that is the worst case of all the products for aspiration of bone marrow, both because it has the ring nut and has no holes on the cannula wall, so it's the worst condition for aspiration. The second device is Totally Remove that is the worst case of all the device for collecting of fragment of bone marrow.

The sterile devices have been utilized for each code in the test samples, under different conditions, in the specific tests listed below:

- 1) To assess the stylet perforation capacity, a needle was introduced in the selected tissue and visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without provoking tears or lacerations, and thus establishing a viable entry path for the cannula. As indicated in the instruction sheet, the needle was introduced in each one of the selected tissues to assess the penetration capacity of the stylet tip.
- 2) As indicated in the instruction sheet, the cannula penetration capacity has been assessed by inserting the device into the selected tissues, up to the bone cortex. In particular, manual testing was conducted to determine whether the specially sharpened cannula tip allowed an effortless penetration, as well as an easy cut without any tissue resistance. Furthermore, once surpassed the bone cortex, the stylet was withdrawn to allow full needle penetration into the medullary cavity for at least 2 cm. and determine whether this procedure presented any difficulty or caused obstruction in the cannula tips.
- 3) Concerning the handle grip, its effectiveness has been repeatedly tested, both on animal tissues and in the vise, to determine whether the handle becomes detached or deformed, rotates on the cannula, or completely breaks once submitted to compression, twisting, or traction. The handle grip has been tested on in vitro tissues which present greater challenges than other tissues, such as the calf femur. The handle underwent a series of stress tests that included compression, traction and twisting, both singularly and collectively administered.
- 4) The adequacy of the Luer-Lock connection was evaluated using two methods, one that involves the use of a buffer based on standards ISO594-1 and another connecting the needle to three syringes of brands and models commonly present in trade and used by doctors to biopsy procedures. (see drawing). About the first test, this consists in the insertion of the ISO 594-1-2 calibrated gauge in the Luer-lock female connector of the tested needles. Exercising a pre-set pressure with the use of a dynamometer, it was concluded that all measurements are within the

prescribed thresholds (minimum, medium, maximum). About the second test, all testing involving needle insertion aimed at determining loss of fluid or any disruption during aspiration procedures. Furthermore, testing was also conducted to determine whether needle-to-syringe connections presented challenges. Three different trials were conducted to assess the suitability of all aspiration procedures and determine the occurrence of any loss of fluid. The first entailed needle-to-syringe connection, by simultaneously sealing the needle tip with a silicon cap (to prevent air from entering the syringe), and pulling the syringe piston backward. In the presence of a leak, the piston can be effortlessly pulled back; on the contrary, well-functioning Luer-lock connectors will not only present difficulties in pulling the piston back, but, once completely pulled, the piston tends to automatically return to its original position. The second test entailed the simulation of aspiration procedures, during which alcohol was aspirated from a glass from a needle correctly connected to its syringe. During both aspiration of the liquid and its release in the glass, leaks were reported between the Luer connectors and/or bubbles or turbulence were visible in the liquid. The third test entailed aspiration of alcohol into the syringe to which was connected a silicon-covered needle. The tester forcefully attempted to discharge the fluid. Particular attention was paid to the general performance of the Luer-lock connectors, or if any leak occurs between the connectors.

5) Testing was also conducted to assess the quantity of the collected sample. As indicated in the instruction sheet, testing entailed the utilization of a needle to conduct mock biopsies on animal bone and flesh, as well as expanded polyurethane and apples. All collected samples were carefully reviewed and measured. For the aspiration we performed a simulation of the aspiration/injection of liquid.

6) Concerning matters of sample integrity, testing was conducted on all collected samples by use of a video-microscope to ensure that in all tests, each collected sample is completely intact and abundant, each sample is cylindrical in shape, full, intact, and free of frays.

All testing yielded the following results:

1) To assess the stylet perforation capacity, a needle was introduced in the selected tissue and visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without provoking tears or lacerations, and thus establishing a viable entry path for the cannula. Insertion was optimal and conducted effortlessly and without any difficulty whatsoever.

2) Concerning the cannula penetration capacity, it was observed that the specially sharpened cannula tip allows easy and trouble-free insertion. Furthermore, once surpassed the bone cortex, the stylet was easily withdrawn to allow full needle penetration into the medullary cavity for at least 2 cm. This procedure was flawlessly conducted without any obstruction to the cannula tip. The integrity of this procedure was furthermore supported by the collection of an intact sample, which provides further proof that the cannula tips never clogged or became obstructed in any way during testing.

3) Concerning the handle grip, its effectiveness has been repeatedly tested, both on animal tissues and in the vise. Testing confirmed that the handle never became detached or deformed in any way; it did not rotate on the cannula, or broke once submitted to compression, twisting, or traction. During in-vise trials, the cannula broke only when submitted to excess force, even though the handle remained intact.

4) The Luer-lock connector is compliant in that all Protocol ISO594-1 gauges testing and the three-syringe trials were deemed fully compliant. Testing also ensured that no loss of liquid and disruptions of any kind occurred, and that the needle-to-syringe connection was easy and trouble-free in all cases.

5) Concerning the quantity of collected sample, each sample was abundant and with a length greater than 1.5 cm. It should be remembered that the acceptance criteria threshold was at least 0.5 cm. for all samples. It bears repeating that each collected fragment was cylindrical in shape and with a minimum length of 1.5 cm.

6) Concerning the integrity of the sample, in all trials each collected sample, whether from animal, apples or expanded polyurethane, was intact and abundant. Each sample was cylindrical in shape, well preserved, intact and free of frays.

In conclusion: All performance testing conducted by using the bone marrow biopsy needles indicate that the device has a good insertion capacity, a good functioning and allows the collection of intact cylindrical tissue samples. All tests also confirm the integrity of the handle. Testing has therefore demonstrated that the device for bone marrow biopsies is fully compliant in matter of effectiveness and safety.

Test report n°67 dated 08/11/2010 for semiautomatic guillotine needles for soft-tissue biopsy

The Biopsybell Needles semiautomatic collect soft tissue samples like breast, kidney, liver, prostate, pancreas by needle insertion.

The purpose of testing is to evaluate:

- 1) The needle perforation capacity (so the capacity of penetration)
- 2) The shot of the needle (and if the cannula cover completely the notch of the stylet)
- 3) The quantity of the collected sample.
- 4) The integrity/quality of the collected sample.

For the present report have been used 'Speedybell doppia corsa' that are the worst case of all the other models of needles of Speedybell's family manufactured by Biopsybell. The five samples have been manufactured in four different lots, having 14G, 16G and 18G diameters and lengths ranging from 70mm, 100 mm, and 150 mm. Performance testing was conducted after proper sterilization of all devices.

The sterile devices have been utilized for each code in the test samples, under different conditions, in the specific tests listed below.

Tests were conducted on the basis of sample collection instructions provided for the needle Speedybell with travel to 10 mm and 20mm.

- 1) To assess the stylet perforation capacity, a needle was introduced in the selected tissue and visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without provoking tears or lacerations, and thus establishing a viable entry path for the cannula. As indicated in the instruction sheet, the needle was introduced in each one of the selected tissues to assess the penetration capacity of the stylet tip.
- 2) Shot of the needle. The operation tests of the release mechanism inside (shoot button needle) were conducted both in air and internally to the animal tissues and in the artificial tissues. If the spring of the needle works well, when there is the shot the tip of the cannula cut the material/tissue and covers completely the notch of the stylet, without leaving open spaces and arriving at the end of its race.
- 3) During the execution of the tests we wanted to test if the cannula covered completely the stylet notch, and we wanted to measure the material collected (liver and muscle used for testing and artificial materials). All collected samples were carefully reviewed and measured.
- 4) We wanted also to evaluate the integrity/quality of the sample collected. Concerning matters of sample integrity, testing was conducted on all collected samples by use of a video-microscope

In the Speedybell doppia corsa the shots were tested both at 1cm and 2 cm and all the tests were performed both in liver tissue, muscle and other tissues (polyurethane and apple).

All testing yielded the following results:

- 1) To assess the stylet perforation capacity, a needle was introduced in the selected tissue and visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without provoking tears or lacerations, and thus establishing a viable entry path for the cannula. Insertion was optimal and conducted effortlessly and without any difficulty whatsoever.
- 2) The shot was always complete and the cannula always covered completely the notch of the stylet. The shot was perfect both in the case of 1cm and 2cm.
- 3) Concerning the quantity of collected sample, each sample was abundant and with a length greater than 0.7 cm for the notch of 1cm and greater than 1.3cm for the notch of 2cm. It should be remembered that the acceptance criteria threshold was at least 0.5 cm for the notch of 1cm and 1cm for the notch of 2cm for all samples. It bears repeating that each collected fragment was cylindrical in shape and with a minimum length of 0.7 cm and 1.3cm.
- 4) Concerning the integrity of the sample, in all trials each collected sample, whether from animal, apples or expanded polyurethane, was intact and abundant. Each sample was cylindrical in shape, well preserved, intact and free of frays.

During testing, no deviations from the anticipated norms and protocols have occurred.

On the basis of the above referenced results, the biopsy needle was fully compliant with all testing requirements; therefore, the sampling procedures to collect intact and consistent tissues is deemed acceptable. Testing has therefore demonstrated that the device is fully compliant in matter of effectiveness and safety. Tests have shown the effectiveness of the device to perform the functions for which it was manufactured. In particular, the pick-up area of 10 mm or 20mm was always full of collected tissue, the tissue is intact and compact inside the notch, the shot of the spring proved to be optimal and internal mechanisms work perfectly.

Test Report n° 68 dated 30/04/2012 for Automatic guillotine needles for soft-tissue biopsy

The automatic needle Ester collect soft tissue samples such as liver by needle insertion. The purpose of this test report is to demonstrate the suitability of the type of device designed for the intended use, evidenced by the fact that the simulation tests of the sampling procedure comply with the specific expectations.

For the present report have been used 'Ester' device of different diameters and length. The samples have been manufactured in different lots, having 16G and 18G diameters and different lengths ranging from 100 mm and 150 mm. Performance testing was conducted after proper sterilization of all devices.

The sterile devices have been utilized for each code in the test samples, under different conditions, in the specific tests listed below.

Tests were conducted on the basis of sample collection instructions provided for the needle Ester and using different animal tissues as liver, muscle or other tissues such as polyurethane and apple.

In particular the purpose of testing is to evaluate:

- 1) The needle perforation capacity (so the capacity of penetration)
- 2) The correct loading of the needle
- 3) The shot of the needle (and if the cannula cover completely the notch of the stylet)
- 4) The quantity of the collected sample.
- 5) The integrity/quality of the collected sample.

The tests in the different tissues have been performed both using the shot with lateral button and back button.

- 1) To assess the stylet perforation capacity, a needle was introduced in the selected tissue and visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without provoking tears or lacerations, and thus establishing a viable entry path for the cannula. As indicated in the instruction sheet, the needle was introduced in each one of the selected tissues to assess the penetration capacity of the stylet tip.
- 2) To test the loading of the needle we try to load the device out from the tissues used and we observed if the lever of charging functions well. In particular with the first loading of the lever, so pushing down on the central loading lever and then releasing it to allow it to return to its initial position, the needle cannula is loaded. Then repeating this operation a second time, so pushing down on the same lever again as far as it will go and then releasing it to allow it to return to its initial position, the needle stylet is loaded. The test of loading has to demonstrate that with the first charging the cannula is correctly loaded and with the second charging the stylet is correctly loaded.
- 3) Shot of the needle. The operation tests of the release mechanism inside (shot button needle) were conducted both in air and internally to the animal tissues and in the artificial tissues. If the spring of the needle works well, when there is the shot the tip of the cannula cut the material/tissue and covers completely the notch of the stylet, without leaving open spaces and arriving at the end of its race. During the execution of the tests we wanted to test if the cannula covered completely the stylet notch, and we wanted to measure the material collected (liver and muscle used for testing and artificial materials). All the tests were performed shooting both with lateral button and side button.
- 4) Testing was also conducted to assess the quantity of the collected sample. As indicated in the instruction sheet, testing entailed the utilization of a needle to conduct biopsies on animal soft tissues as well as expanded polyurethane and apples. All collected samples were carefully reviewed and measured.
- 5) Concerning matters of sample integrity, testing was conducted on all collected samples by use of a video-microscope.

All testing yielded the following results:

- 1) To assess the stylet perforation capacity, a needle was introduced in the selected tissue and visually tested to ensure that the stylet tip could easily and effortlessly penetrate the tissue without provoking tears or lacerations, and thus establishing a viable entry path for the cannula. Insertion was optimal and conducted effortlessly and without any difficulty whatsoever.
- 2) The loading of the cannula and the stylet resulted good in all the cases. The 2 components remained loaded and the loading has been realized with the first try.
- 3) The shot was always complete and the cannula always covered completely the notch of the stylet. The shot was perfect both with lateral and side button.
- 4) Concerning the quantity of collected sample, each sample was abundant and with a length greater than 1 cm for all samples. It bears repeating that each collected fragment was cylindrical in shape and with a minimum length of 1cm.
- 5) Concerning the integrity of the sample, in all trials each collected sample, whether from animal, apples or expanded polyurethane, was intact and abundant. Each sample was cylindrical in shape, well preserved, intact and free of frays.

During testing, no deviations from the anticipated norms and protocols have occurred. On the basis of the above referenced results, the needle was fully compliant with all testing requirements; therefore, the sampling procedures to collect intact and consistent tissues is deemed acceptable.

In conclusion testing has therefore demonstrated that the device is fully compliant in matter of effectiveness and safety. Tests have shown the effectiveness of the device to perform the functions for which it was manufactured. In particular, the pick-up area was always full of collected tissue, the tissue is intact and compact inside the notch, the shot of the spring proved to be optimal

and internal mechanisms work perfectly. All the mechanisms of loading and shooting (with lateral and back button) work well.

Comparison with predicate devices:

Premise: This 510K application includes 3 families of products for biopsy:

- 1) Needle for bone-marrow biopsy: FAMILY N°1
- 2) Semiautomatic guillotine needles for soft-tissues biopsy: FAMILY N°2
- 3) Automatic needles for soft-tissues biopsy: FAMILY N°3

FAMILY N°1

Substantial Equivalence: We claim that our **Needles for bone-marrow biopsy** are substantially equivalent to:

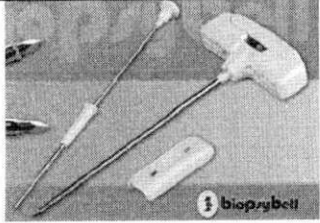
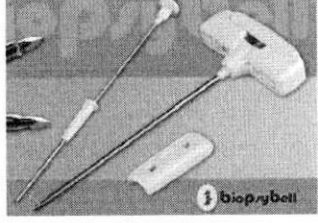
- OSTEObELL Bone Marrow Needle by Biopsybell s.a.s., 510(k): K011104;

And the devices are identical in the material, principles and basic function. They have the same intended use and differ only in optical design aspects.

The usability of our devices has been proven, so that any disadvantage in using our devices is unlikely.

Non-clinical tests concerning the functionality and efficiency were performed to evaluate the substantial equivalence of our devices.

The Chart below summarizes the similarities and differences:

OSTEOBELL 'T' of this bundled application	OSTEOBELL of the past application (K011104): PREDICATE DEVICE
	
IS EXACTLY THE SAME PRODUCT	
Materials: stainless steel AISI 304 and ABS	Materials: stainless steel AISI 304 and ABS
Manufacturer: Biopsybell	Manufacturer: Biopsybell
Production Establishment: Biopsybell	Production Establishment: Biopsybell
Suppliers of the first materials (of Biopsybell)	Suppliers of the first materials (of Biopsybell)
Manufacturing process (of Biopsybell)	Manufacturing process (of Biopsybell)

Personnel that manufacture the device (of Biopsybell)	Personnel that manufacture the device (of Biopsybell)
Mechanical equipment (of Biopsybell)	Mechanical equipment (of Biopsybell)
Technical specifications, measures, quality procedures of Biopsybell	Technical specifications, measures, quality procedures of Biopsybell
Packaging (PVC blister + medical paper)	Packaging (PVC blister + medical paper)
EO sterilization process (same establishment, by the same personnel, with the same parameter and validation of the process)	EO sterilization process (same establishment, by the same personnel, with the same parameter and validation of the process)
intended use: bone-marrow biopsy	intended use: bone-marrow biopsy
instructions for use (of Biopsybell)	instructions for use (of Biopsybell)
Frequency: single use	Frequency: single use
Functioning tests (of Biopsybell)	Functioning tests (of Biopsybell)
Drawings and measures (of Biopsybell)	Drawings and measures (of Biopsybell)
Monitoring: ultrasound	Monitoring: ultrasound

There are many variants of the needle Osteobell 'T' in this bundled and all these variants are different only for little details as for example: the tip (in the Osteobell the tip is a trocar tip and in other devices it's triple sharpened tip) and the choice between the different tips depends most of all from the manual skill of the doctor; the presence of few holes in the distal end of the cannula (and this increase the aspiration of the bone marrow without changing the functioning at all); the presence of a ring nut that allows to adjust the depth reached during the biopsy before the operation, but also in this case without changing the functioning or the intended use of the device. So all these little differences from the variants of Needles for bone-marrow biopsy and the Osteobell of the predicate device are not critical to the intended use of the device and do not affect the safety and the effectiveness of the device when used as labeled.

For all the evaluations and the demonstration of the substantial equivalence, see the report of comparison in the section C.

FAMILY N°2

Substantial Equivalence: We claim that our **Semiautomatic guillotine needles for soft-tissue biopsy** are substantially equivalent to:

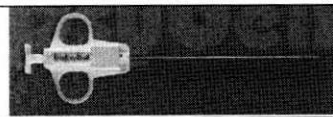

- SPEEDYBELL by Biopsybell s.a.s., 510(k): K010735;

The devices are identical in the material, principles and basic function. They have the same intended use and differ only in optical design aspects.

The usability of our devices has been proven, so that any disadvantage in using our devices is unlikely.

Non-clinical tests concerning the functionality and efficiency were performed to evaluate the substantial equivalence of our devices.

The Chart below summarizes the similarities and differences:

SPEEDYBELL of this bundled application	SPEEDYBELL (K010735) of the past application: PREDICATE DEVICE
	
IS EXACTLY THE SAME PRODUCT	
Materials: stainless steel AISI 304 and	Materials: stainless steel AISI 304 and

PC	PC
Manufacturer: Biopsybell	Manufacturer: Biopsybell
Production Establishment: Biopsybell	Production Establishment: Biopsybell
Suppliers of the first materials (of Biopsybell)	Suppliers of the first materials (of Biopsybell)
Manufacturing process (of Biopsybell)	Manufacturing process (of Biopsybell)
Personnel that manufacture the device (of Biopsybell)	Personnel that manufacture the device (of Biopsybell)
Mechanical equipment (of Biopsybell)	Mechanical equipment (of Biopsybell)
Technical specifications, measures, quality procedures of Biopsybell	Technical specifications, measures, quality procedures of Biopsybell
Packaging (two-ply bags of medical paper and transparent film)	Packaging (two-ply bags of medical paper and transparent film)
EO sterilization process (same establishment, by the same personnel, with the same parameter and validation of the process)	EO sterilization process (same establishment, by the same personnel, with the same parameter and validation of the process)
intended use: semiautomatic guillotine needle for soft-tissue biopsy	intended use: semiautomatic guillotine needle for soft
instructions for use (of Biopsybell)	instructions for use (of Biopsybell)
Frequency: single use	Frequency: single use
Functioning tests (of Biopsybell)	Functioning tests (of Biopsybell)
Drawings and measures (of Biopsybell)	Drawings and measures (of Biopsybell)
Monitoring: ultrasound	Monitoring: ultrasound

A possible variant of the Speedybell is the Speedybell doppia corsa with the same function and intended use, but with a little changing (possibility to chose between a notch of 1cm or 2cm in the same needle). As described in detail in the 'Device description' in the 'Speedybell doppia corsa' needle the doctor has the possibility to have a sampling area of 1 cm or 2 cm in the same needle. The sampling area of the Speedybell is only 2cm. This possible variant of the Speedybell doesn't change the functioning or the intended use of the device.

The other variant created by Biopsybell in response to the doctor's needs is the presence of an Introducer needle (in the 'Speedybell & Introduuttore' device and in the 'Speedybell doppia corsa & Introduuttore' device. The use of the Introducer is only more comfortable and practical for the doctor in order to have a 'guide' in which enter with the needle, but this doesn't change the functioning and the intended use or the feature of the semiautomatic needle.

So these little differences from the variants of Semiautomatic guillotine needles for soft-tissue biopsy and the Speedybell of the predicate device are not critical to the intended use of the device and do not affect the safety and the effectiveness of the device when used as labeled.

FAMILY N°3

Substantial Equivalence: We claim that our **Automatic guillotine needles for soft-tissue biopsy** are substantially equivalent to:

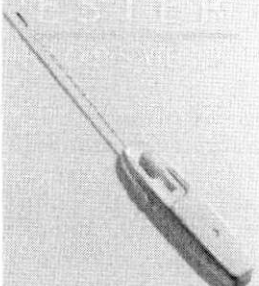
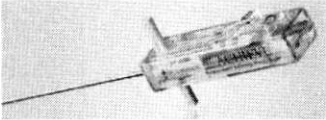
- TEMNO ACHIEVE® BIOPSY NEEDLE by Bauer Medical, Inc., distributed by CareFusion Corporation, 510(k): K960064

The devices are identical in the material, principles and basic function. They have the same intended use and differ only in optical design aspects.

The usability of our devices has been proven, so that any disadvantage in using our devices is unlikely.

Non-clinical tests concerning the functionality and efficiency were performed to evaluate the substantial equivalence of our devices.

The Chart below summarizes the similarities and differences:

ESTER of this bundled application	ACHIEVE® (K960064): PREDICATE DEVICE
	
Human tissues in which the device is applied: liver	Human tissues in which the device is applied: liver
Intended use: biopsy of soft tissues	Intended use: biopsy of soft tissues
Action mechanism: automatic gun with guillotine system	Action mechanism: automatic gun with guillotine system
Buttons: two different sites/buttons for loading and for shooting	Buttons: two different sites/buttons for loading and for shooting
LOADING SYSTEM: charging in two steps: first pushing down the charging lever is loaded the cannula and then with the second pushing down is loaded the stylet	LOADING SYSTEM: charging in two steps: first pushing down the charging lever is loaded the cannula and then with the second pushing down is loaded the stylet
SHOOTING SYSTEM: the shot can happened in two different ways, in one step or two steps	SHOOTING SYSTEM: the shot can happened in two different ways, in one step or two steps
Advantage: use one hand only in order to realize the biopsy	Advantage: use one hand only in order to realize the biopsy
diameters: 14G, 16G, 18G, 20G	diameters:14G, 16G, 18G, 20G
Length: 10cm, 15cm, 20cm, 25cm, 30cm	Length:11cm, 15cm, 20cm.
Notch of the stylet: 2cm	Notch of the stylet: 2cm
Echogenic marker	Echogenic marker
Materials: plastic case/ steel needle/ metal springs inside	Materials: plastic case/ steel needle/ metal springs inside
Single use	Single use
Possible use of the Introducer needle	Possible use of the Introducer needle

One difference between the two devices is that for the shooting in the 'Ester' there is only one button. In the 'Achieve' there are two buttons for the firing one next to the other, in order to make the shooting in one step only or in two steps. The two buttons of the Achieve are very near, so in the same position. The choice of Biopsybell to have one button only, was an improvement, because this allow to the doctor not to change position of the hand/finger during the shooting, but operating always in the same position, reducing the possibility of movement of the device during the biopsy.

The other difference is that in the Ester there are two possibilities of choice of the fire button (lateral and back button), depending from the comfort and dexterity of the doctor. This is only an improvement in the device of Biopsybell, realized only to facilitate the comfort and to meet manual skill of the physician of the doctor.

So these little differences from the Automatic guillotine needles for soft-tissue biopsy of Biopsybell and the predicate device are not critical to the intended use of the device and do not affect the safety and the effectiveness of the device when used as labeled.

- For all the evaluations and the demonstration of the substantial equivalence, see the report of comparison in the section C.

Conclusions statement

The subject devices "**Needles for bone-marrow biopsy**", "**Semiautomatic guillotine needles for soft-tissue biopsy**", "**Automatic guillotine needles for soft-tissue biopsy**" are as safe, as effective, and perform as well as the predicate devices. The performed non-clinical tests demonstrate the safety of the subject device's performance, sterility and biocompatibility.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2014

Biopsybell S.R.L
Mr. Willer Ghelfi
62 Gerdes Avenue
Verona, New Jersey 07004

Re: K130616

Trade/Device Name: Manual Bone Marrow Biopsy Needles, Semi-Automatic Biopsy
Needles, Automatic Biopsy Needles
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology- urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: January 7, 2014
Received: January 13, 2014

Dear Mr. Ghelfi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua  Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)
K1330616

Device Name
MANUAL NEEDLES FOR BONE MARROW BIOPSY

Indications for Use (Describe)

- OSTEOBELL 'T': Needle for bone-marrow biopsy
- ORION: Needle for bone-marrow biopsy
- ILIAC-MARROW: Needle for bone-marrow biopsy
- OBSTERN: Needle for bone-marrow biopsy
- STERNOBELL: Needle for bone-marrow biopsy
- TOTALLY REMOVE: Needle for bone-marrow biopsy
- UNLUX SYSTEM: Needle for bone-marrow biopsy
- OSTEOBELL EXPLANT: Needle for bone-marrow explant
- ORION EXPLANT: Needle for bone-marrow explant
- ILIAC-MARROW EXPLANT: Needle for bone-marrow explant
- OBSTERN EXPLANT: Needle for bone-marrow explant
- STERNOBELL EXPLANT: Needle for bone-marrow explant

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Long H. Chen

Digitally signed by Long H. Chen -A
DN: cn=Long H. Chen, o=FDA, ou=People, ou=Long H. Chen -A,
c=US, email=long.h.chen@fda.hhs.gov

for BSA

(Division Sign-off)

Division of Surgical Devices

510 (k) Number: K130616

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

Indications for Use

510(k) Number (if known)
K130616

Device Name
SEMI-AUTOMATIC GUILLOTINE NEEDLES

Indications for Use (Describe)

- SPEEDYBELL: SEMI-AUTOMATIC GUILLOTINE NEEDLE FOR SOFT-TISSUE BIOPSY (SUCH AS BREAST, KIDNEY, LIVER, PROSTATE)
- SPEEDYBELL & INTRODUTTORE: SEMI-AUTOMATIC GUILLOTINE NEEDLE FOR SOFT-TISSUE BIOPSY (SUCH AS BREAST, KIDNEY, LIVER, PROSTATE)
- SPEEDYBELL DOPPIA CORSA: SEMI-AUTOMATIC GUILLOTINE NEEDLE FOR SOFT-TISSUE BIOPSY (SUCH AS BREAST, KIDNEY, LIVER, PROSTATE)
- SPEEDYBELL DOPPIA CORSA & INTRODUTTORE: SEMI-AUTOMATIC GUILLOTINE NEEDLE FOR SOFT-TISSUE BIOPSY (SUCH AS BREAST, KIDNEY, LIVER, PROSTATE)

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)


☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Long H. Chen


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c=US, email=long.h.chen@FDA.gov, o=U.S. Government, ou=HHS,
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Date: 2014.02.07 12:43:01 -0500

for BSA

(Division Sign-off)

510(k) Number: K130616

Division of Surgical Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number (if known)
K130616

Device Name
AUTOMATIC GUILLOTINE NEEDLE

Indications for Use (Describe)

- ESTER: AUTOMATIC GUILLOTINE NEEDLE FOR SOFT-TISSUE BIOPSY (SUCH AS LIVER)
- ESTER & INTRODUTTORE: AUTOMATIC GUILLOTINE NEEDLE FOR SOFT-TISSUE BIOPSY (SUCH AS LIVER)

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)


☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Long H. Chen

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2014.02.07 12:42:27 -0500
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ou=FDA, ou=CDRH, email=Long.H.Chen@FDA.gov,
c=US

for BSA

(Division Sign-off)

510(k) Number: K130616

Division of Surgical Devices